MAR 1 3 2001

K001353
APPENDIX III
510(k) Summary

Device Name: Memograph® Staple System (OSStaple™)

BioMedical Enterprises, Inc. (BME) intends to introduce additional indications for the Memograph® Staple System consisting of shape memory Nitinol staples (the "OSStaple™") and accessories for setting and warming the staples to achieve compression.

a. Submittor Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245
Telephone: (210) 677-0354
Contact: Dr. W. Casey Fox (President)

Date Prepared: February 28, 2001

b. Classification name: Staple, Fixation, Bone
Common/Usual Name: Bone staple
Proprietary Name: Memograph® Staple System, OSStaple™

c. Intended Use:

Indications for the OSStaple™ are fixation of unloaded craniofacial bone fractures and cranioplasty. The OSStaple™ is contraindicated for craniofacial patients with a skull thickness less than the selected prong length.

d. Device Description

The Memograph® Staple system consists of two and four prong staples for bone fragment and osteotomy fixation and joint arthrodesis and fixation of soft tissue to bone such as in anterior cruciate ligament reconstruction. The staple is fabricated from Nitinol. The staple's prongs are parallel during insertion. Application of an electrical current from the Warmsystem to the staple causes its prong to deflect inward. This inward deflection causes staple retention and compression across the osteotomy or arthrodesis site.

e. Substantial Equivalence:

The OSStaple™ shares similar features and function with similar devices by:

- Aesculap, Inc.
- Synthes (USA)
- Stryker Leibinger

These devices form a bridge with implantable metal across a fracture or osteotomy site. The bridge is mechanically anchored in sound cortical bone on adjacent sides of the fracture or osteotomy either by screws or by pinning. Shape memory alloys, when deflected, mimic the anchoring effect of the screw thread inclined plane on the cortex. These devices have been classified as Class II devices (e.g. 21 CFR 882.5330 and 882.5360.

The Warmsystem heating unit was approved via 510(k) K993714 and modifications are not required for the additional indications. The Warmsystem uses the joule (heating) effect of electrical current in a conductor to increase the temperature of the Nitinol staple (as the conductor) allowing it to return to its stable position thereby causing compression. Internal circuitry controls the heating effect and tissue damage by limiting current and time such that a limiting metal temperature of 55°C is achieved in a maximum of 5 seconds.

(Signature)

W. Casey Fox, Ph.D. P.E.
President
BioMedical Enterprises, Inc.

3/13/01
(Date)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

W. Casey Fox, Ph.D., PE
BioMedical Enterprises, Inc.
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K001353
Trade Name: OSStaple™ Memograph® Staple System
Regulatory Class: II
Product Code: HBW
Dated: December 14, 2000
Received: December 15, 2000

Dear Dr. Fox:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001353

APPENDIX II

Indication For Use

Device Name: Memograph® Staple System (OSStaple™)

Indications for the OSStaple™ are fixation of unloaded craniofacial bone fractures and cranioplasty. The OSStaple™ is contraindicated for craniofacial patients with a skull thickness less than the selected prong length.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001353